

UNITED STATES DEFINED FOR THE DISTRICT OF 1	ISTRICT COURTH CLERKS OFFICE MASSACHUSETTS
ABBOTT LABORATORIES,	2002 FEB 20 A H: 22 U.S. DISTRICT COURT DISTRICT OF HASS.
Plaintiff, v.) Civil Action No. 98CV10674-GAO
INVERNESS MEDICAL TECHONOLOGY, INC., and PRINCETON BIOMEDITECH CORPORATION,)))
Defendants.))

ABBOTT LABORATORIES' MOTION FOR LEAVE TO SUPPLEMENT ITS COMPLAINT

Pursuant to Rule 15(d) of the Federal Rules of Civil Procedure, plaintiff Abbott Laboratories moves for leave to supplement its complaint (a copy of which is attached as Exhibit A). The amended complaint adds claims against both defendants for infringement of United States Patent 6,020,147, issued February 1, 2000 (attached as Exhibit B). Abbott's request falls squarely within the scope of Rule 15(d), which authorizes amendment "upon reasonable notice and upon such terms as are just." The claims to be added are inextricably tied to the facts presently at issue in this case. Moreover, Abbott has acted promptly in bringing this motion, and the addition of these claims will not result in undue delay in the matter's disposition. These positions are set out more fully in the attached memorandum in support of this motion.

CERTIFICATION PURSUANT TO LOCAL RULE 7.1

Counsel for the parties conferred in a good faith effort to resolve or narrow the issues presented in this motion. No agreement was reached.

Boston, Massachusetts February 20, 2002 Respectfully submitted, **ABBOTT LABORATORIES**By its Attorneys,

Lee Carl Bromberg, BBO # 058480 Joel R. Leeman, BBO # 292070 Erik Paul Belt, BBO # 558620 BROMBERG & SUNSTEIN LLP 125 Summer Street Boston, MA 02110 (617) 443-9292

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CERTIFICATE OF SERVICE

I certify that, on the above date, a true copy of this document was served by mail on counsel of record for each other party. $\int \Delta A$

Joel R. Leeman

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	IN CLERKS OFFICE Exhibit A
UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSE IN STRICT COURT DISTRICT OF MASS.	
ABBOTT LABORATORIES,))
Plaintiff,)
v.	Civil Action No. 98CV10674-GAO
INVERNESS MEDICAL TECHNOLOGY, INC., and PRINCETON BIOMEDITECH CORPORATION,)))
Defendants.))

AMENDED COMPLAINT

Plaintiff Abbott Laboratories ("Abbott") complains against Inverness Medical Techonology,
Inc. ("Inverness") and Princeton BioMeditech Corporation ("PBM") as follows:

PARTIES

- 1. Abbott is a corporation organized and existing under the laws of the State of Illinois, and has its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois.
- 2. Abbott's principal business is the discovery, development, manufacture, and sale of health care products, including diagnostic instruments, tests, and reagents. Abbott's products include rapid, self-performing immunoassays for the qualitative determination of substances in human body fluids.
- 3. On information and belief, Inverness is a corporation organized and existing under the laws of the State of Delaware, and has its principal place of business in Waltham, Massachusetts.

Inverness is doing business in this judicial district in that it offers for sale and sells products in this district, including, but not limited to, the products at issue in this case.

- 4. On information and belief, PBM is a corporation organized and existing under the laws of the State of New Jersey, and has its principal place of business in Monmouth Junction, New Jersey. PBM is doing business in this judicial district in that it offers for sale and sells products in this district, including, but not limited to, the products at issue in this case.
 - 5. Inverness manufactures, markets, and/or sells rapid self-test diagnostic products.
 - 6. PBM manufactures, markets, and/or sells rapid self-test diagnostic products.

JURISDICTION AND VENUE

- 7. This is an action for patent infringement arising under the Patent Laws of the United States, Title 35, United States Code. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1331 (federal question), 1332 (diversity) and 1338(a) (patent actions).
 - 8. Venue in this District is proper pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENTS INFRINGED

- 9. On August 5, 1997, the United States Patent and Trademark Office ("PTO") issued United States Patent No. 5,654,162, entitled "Chemical Analysis Apparatus and Method" (the "'162 patent"). A copy of the '162 patent is attached to this Complaint as Exhibit A.
- 10. On December 17, 1991, the PTO issued United States Patent No. 5,073,484, entitled "Quantitative Analysis Apparatus and Method" (the "'484" patent"). A copy of the '484 patent is attached to this Complaint as Exhibit B.
 - 11. On February 1, 2000, the PTO issued United States Patent No. 6,020,147, entitled

"Chemical Analysis Apparatus and Method" (the "'147 patent"). A copy of the '147 patent is attached to this Complaint as Exhibit C.

- 12. Pursuant to 35 U.S.C. § 282, the '162, '484, and '147 patents, and each of their claims, are presumed valid.
- 13. Patrick E. Guire and Melvin J. Swanson are the inventors of the '162, '484, and '147 patents. Both inventors assigned their rights in the '162, '484, and '147 patents to Bio-Metric Systems, Inc., now known as SurModics, Inc. ("BSI").
- 14. Pursuant to a license agreement with BSI, Abbott is the worldwide, exclusive licensee of the '162, '484, and '147 patents (collectively, "the Abbott patents"). Pursuant to the agreement, Abbott has the right to bring suit against infringers of the Abbott patents, including Inverness and PBM.

COUNT I INVERNESS'S INFRINGEMENT OF THE '162 PATENT

- 15. Abbott realleges and reincorporates paragraphs 1 through 14 of its Complaint as if fully set forth herein.
- 16. In violation of 35 U.S.C. § 271(a), Inverness has been and still is infringing, contributing to, and actively inducing infringement of the '162 patent by manufacturing, using, selling, or offering for sale products (the "Inverness Products") within the United States that are covered by one or more claims of the '162 patent.
 - 17. The infringing Inverness Products include, but are not limited to, the following:
 - a. SelfcareTM "early Pregnancy" Test; a rapid, self-performing immunoassay

(sold in cassette and in-stream formats) for the qualitative detection of human chorionic gonadotropin ("hCG") in human urine for the early detection of pregnancy;

- b. Selfcare Early Ovulation Predictor Test, a rapid, self-performing immunoassay for the qualitative detection of luteinizing hormone ("LH") in human urine to detect ovulation;
- c. Other rapid test kits for detection and diagnosis of strep, and other health conditions; and,
- d. Private label or store brand test kits made and manufactured by Inverness.
- 18. Inverness has profited and continues to profit from its manufacture, distribution, use, and sale of the infringing Inverness Products.
- 19. Upon information and belief, Inverness's infringement of the '162 patent has been and continues to be willful, wanton, and deliberate.
- 20. Abbott has been and continues to be damaged and irreparably harmed by Inverness's infringement of the '162 patent.

COUNT II INVERNESS'S INFRINGEMENT OF THE '484 PATENT

- 21. Abbott hereby realleges and reincorporates paragraphs 1 through 14 and 17 of its Complaint as if fully set forth herein.
- 22. In violation of 35 U.S.C. § 271(a), Inverness has been and still is infringing, contributing to, and actively inducing infringement of the '484 patent by manufacturing, using,

selling, or offering for sale within the United States the Inverness Products, which are covered by one or more claims of the '484 patent.

- 23. Inverness has profited and continues to profit from its manufacture, distribution, use, and sale of the infringing Inverness Products.
- 24. Upon information and belief, Inverness's infringement of the '484 patent has been and continues to be willful, wanton, and deliberate.
- 25. Abbott has been and continues to be damaged and irreparably harmed by Inverness's infringement of the '484 patent.

COUNT III INVERNESS'S INFRINGEMENT OF THE '147 PATENT

- 26. Abbott hereby realleges and reincorporates paragraphs 1 through 14 and 17 of its Complaint as if fully set forth herein.
- 27. In violation of 35 U.S.C. § 271(a), Inverness has been and still is infringing, contributing to, and actively inducing infringement of the '147 patent by manufacturing, using, selling, or offering for sale within the United States the Inverness Products, which are covered by one or more claims of the '147 patent.
- 28. Inverness has profited and continues to profit from its manufacture, distribution, use, and sale of the infringing Inverness Products.
- 29. Upon information and belief, Inverness's infringement of the '147 patent has been and continues to be willful, wanton, and deliberate.

30. Abbott has been and continues to be damaged and irreparably harmed by Inverness's infringement of the '147 patent.

COUNT IV PBM'S INFRINGEMENT OF THE '162 PATENT

- 31. Abbott hereby realleges and reincorporates paragraphs 1 through 14 of its Complaint as if fully set forth herein.
- 32. On information and belief, in violation of 35 U.S.C. § 271(a), PBM has been and still is infringing, contributing to, and actively inducing infringement of the '162 patent by manufacturing, using, selling, or offering for sale products (the "PBM Products") within the United States that are covered by one or more claims of the '162 patent.
 - 33. On information and belief, PBM manufactures the Inverness Products.
- 34. In addition to the Inverness Products, the PBM Products include, but are not limited to, the following:
 - a. Biostrip® P One-Step Pregnancy Test Strip, BioSign® 1 One-Step Pregnancy
 Test Strip, LifeSign® 1 One-Step Home Pregnancy Test and LifeSign Plus®
 One-Step Home Pregnancy Test, all of which are rapid, self-performing
 immunoassays for the qualitative detection of hCG in human urine for the
 early detection of pregnancy;
 - b. OvuSign™ One-Step Ovulation Predictor Test, a rapid, self-performing immunoassay for the qualitative detection of LH in human urine for detecting ovulation; and

- c. Other rapid test kits for detection and diagnosis of strep, and other health conditions; and,
- d. Private label test kits made and sold by PBM.
- 35. PBM has profited and continues to profit from its manufacture, distribution, use, and sale of the infringing PBM Products.
- 36. Upon information and belief, PBM's infringement of the '162 patent has been and continues to be willful, wanton, and deliberate.
- 37. Abbott has been and continues to be damaged and irreparably harmed by PBM's infringement of the '162 patent.

COUNT V PBM'S INFRINGEMENT OF THE '484 PATENT

- 38. Abbott hereby realleges and reincorporates paragraphs 1 through 14, 33, and 34 of its Complaint as if fully set forth herein.
- 39. In violation of 35 U.S.C. § 271(a), PBM has been and still is infringing, contributing to, or actively inducing infringement of the '484 patent by manufacturing, using, selling or offering for sale in the United States the PBM Products, which are covered by one or more claims of the '484 patent.
- 40. PBM has profited and continues to profit from its manufacture, distribution, use and sale of the infringing PBM Products.
 - 41. Upon information and belief, PBM's infringement of the '484 patent has been and

continues to be willful, wanton, and deliberate.

42. Abbott has been and continues to be damaged and irreparably harmed by PBM's infringement of the '484 patent.

COUNT VI PBM'S INFRINGEMENT OF THE '147 PATENT

- 43. Abbott hereby realleges and reincorporates paragraphs 1 through 14, 33, and 34 of its Complaint as if fully set forth herein.
- 44. In violation of 35 U.S.C. § 271(a), PBM has been and still is infringing, contributing to, or actively inducing infringement of the '147 patent by manufacturing, using, selling or offering for sale in the United States the PBM Products, which are covered by one or more claims of the '147 patent.
- 45. PBM has profited and continues to profit from its manufacture, distribution, use and sale of the infringing PBM Products.
- 46. Upon information and belief, PBM's infringement of the '147 patent has been and continues to be willful, wanton, and deliberate.
- 47. Abbott has been and continues to be damaged and irreparably harmed by PBM's infringement of the '147 patent.

WHEREFORE, Abbott respectfully asks this Court to enter judgment for Abbott and against Inverness and PBM, and to grant Abbott the following relief:

(a) An order pursuant to 35 U.S.C. § 271 finding that Inverness infringes the Abbott patents;

- (b) An order pursuant to 35 U.S.C. § 271 finding that PBM infringes the Abbott patents;
- (c) An order pursuant to 35 U.S.C. § 283 preliminarily and permanently enjoining Inverness and PBM from infringing the Abbott patents;
- (d) An award of damages pursuant to 35 U.S.C. § 284 adequate to compensate Abbott for Inverness's infringement of the Abbott patents, and an accounting to determine the proper amount of such damages;
- (e) An award of damages pursuant to 35 U.S.C. § 284 adequate to compensate Abbott for PBM's infringement of the Abbott patents, and an accounting to determine the proper amount of such damages;
- (f) A three-fold increase in damages as a result of Inverness's and PBM's willful, wanton, and deliberate acts of infringement;
- (g) An award pursuant to 35 U.S.C. § 284 of costs and prejudgment and postjudgment interest on Abbott's compensatory damages;
- (h) An award pursuant to 35 U.S.C. § 285 of Abbott's attorneys' fees incurred in this action;
- (i) An order directing the recall of all existing Inverness or PBM Products that infringe the '162, '484, and/or the '147 patent; and
- (j) Such further relief as this Court deems just and proper.

JURY DEMAND

Abbott hereby demands a trial by jury.

Date: March ____, 2002

Respectfully submitted,
ABBOTT LABORATORIES
By its Attorneys,

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CERTIFICATE OF SERVICE

I certify that, on the above date, a true copy of this document was served by mail on counsel of record for each other party.

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